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Literature review

Otitis media and spinal manipulative therapy: a literature review

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Abstract

Objective: Otitis media (OM) is one of the common conditions for doctor visits in the pediatric population. Spinal manipulation therapy (SMT) may be a potential conservative treatment of OM. The purpose of this study is to review the literature for OM in children, outlining the diagnosis of OM, SMT description, and adverse event notation.

Methods: Databases (PubMed, Cochrane Library, Cumulative Index to Nursing and Allied Health, Index to Chiropractic Literature, The Allied and Complementary Medicine, and Alt Health Watch) were queried and hand searches were performed to identify relevant articles. All potential studies were independently screened for inclusion by both authors. The inclusion criteria were as follows: written in the English language, addressed OM, involved human participants 6 years or younger, and addressed SMT. Studies were evaluated for overall quality using standardized checklists performed independently by both authors.

Results: Forty-nine articles were reviewed: 17 commentaries, 15 case reports, 5 case series, 8 reviews, and 4 clinical trials. Magnitude of effect was lower in higher-quality articles. No serious adverse events were found; minor transient adverse effects were noted in 1 case series article and 2 of the clinical trials.

Conclusions: From the studies found in this report, there was limited quality evidence for the use of SMT for children with OM. There are currently no evidence to support or refute using SMT for OM and no evidence to suggest that SMT produces serious adverse effects for children with OM. It is possible that some children with OM may benefit from SMT or SMT combined with other therapies. More rigorous studies are needed to provide evidence and a clearer picture for both practitioner and patients.

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Introduction

Otitis media (OM) is one of the primary conditions for which antibiotics are prescribed in the United States.¹ Failure to distinguish acute otitis media (AOM) from otitis media with effusion (OME) is a possible reason for the use of antibiotics when they are not indicated, and this may contribute to the development of antibiotic-resistant organisms. Acute OM and OME both are upper respiratory tract infections, but children with AOM also have pain and fever.² The current recommendation for the treatment of AOM is to use an antibacterial agent (usually amoxicillin).³ Antimicrobial therapy is not recommended for patients with OME because it typically resolves spontaneously.² Because of the concerns of increasing antibiotic-resistant infections and overuse of antibiotics, other methods for conservative care for the common condition of OME are needed. Methods traditionally associated with complementary and alternative medicine (CAM) are usually conservative and do not include pharmaceutical drugs or surgery. Currently, CAM is not considered a potential treatment of either AOM or OME because of limited evidence in the literature.^{3,4}

In addition to musculoskeletal disorders, both the chiropractic and osteopathic professions have claimed that spinal manipulation therapy (SMT) may alleviate disorders involving visceral organs, such as OME.^{5,6} Hypotheses regarding how SMT accomplishes this generally attribute the effects of SMT to biomechanical changes produced in the spine, which subsequently mediate changes in sympathetic or parasympathetic nerve activity.^{5,6}

Certain chiropractic and osteopathic manipulative techniques address the function of cranial structures (including intraoral structures) for treatment of OM.⁷ These structures may directly affect the Eustachian tube (ET), which is thought to be the primary structure involved in reoccurrence of OM.⁸ The ET has an increase in goblet cells during and up to at least 6 months after OM regardless of the bacterium causing the condition. Otitis media causes an increased secretory capacity of the ET. This increase may contribute to the excessive mucus and deteriorated ET function. These factors could also predispose the patient to the reoccurrence of OM or to a more aggressive middle ear complication.

Another hypothesis, which also indirectly involves the ET, is the impact of cervical manipulation on the lymphatic and muscular systems. Lymphatic flow requires muscular contractions, arterial pulsations, and external compression of body tissues. It is hypothe-

sized that restricted joint movement within the cervical spine may result in muscle hypertonicity restricting lymphatic drainage away from the cranial region. This hypothesis suggests that cervical SMT reduces tension within hypertonic muscles, thus increasing lymphatic drainage.⁹

At present, there has not been a review of the literature summarizing the effects of spinal manipulation therapy (SMT) on OM or the safety of SMT for treating OM. The purpose of this study was to review the literature on the treatment effects of SMT and/or mobilization (including both chiropractic and osteopathic approaches) for all types of OM. This study also evaluates the literature for information relating to the diagnosis of OM, SMT description, and reported adverse events.

Methods

Sources of information

Relevant studies were identified using the following databases: PubMed, Cochrane Library (CENTRAL), Cumulative Index to Nursing and Allied Health (CINAHL), Index to Chiropractic Literature (ICL), The Allied and Complementary Medicine (AMED), and Alt Health Watch. All databases were searched from inception thru March 2011 (Fig 1). We checked reference lists of relevant studies to identify cited articles not captured by electronic searches.

Selection criteria

Because there are few randomized controlled trials (RCTs) and other higher levels of evidence for CAM therapies, such as SMT, we included all levels of evidence. Allowing all levels of evidence provides a comprehensive review of the current state of literature on this subject.

Articles were included if they met the following criteria: (1) written in the English language, (2) addressed OM (acute or chronic), (3) involved human participants 6 years or younger, (4) addressed SMT or osteopathic manipulative therapy to a spinal segment or cranial bone.

Search terms and delimiting

Search terms for all databases (except 1) included *otitis media* OR *otitis media with effusion* OR *glue*

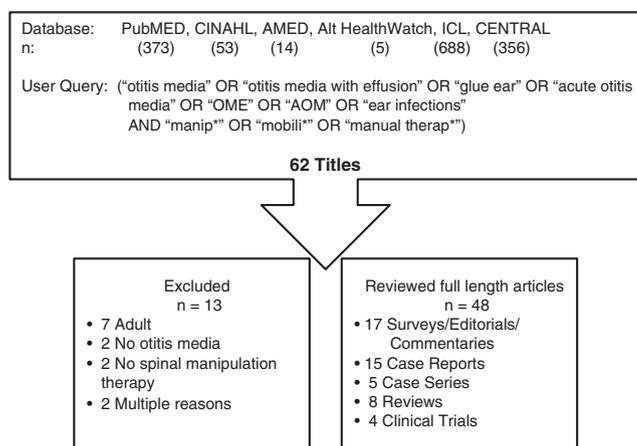


Fig 1. Flowchart showing the retrieval process of literature included in this narrative review.

ear OR acute otitis media OR OME OR AOM OR ear infections AND manip* OR mobili* OR manual therap*. The ICL database was only searched using otitis media OR otitis media with effusion OR glue ear OR acute otitis media OR OME OR AOM OR ear infections. All were searched for references written in English and involved human participants.

All titles and abstracts of potential relevant studies were then independently screened for inclusion by both authors. Any disagreements about inclusion were discussed until consensus was reached.

Quality assessment

Studies included in the review underwent a quality assessment performed independently by both assessors, with consensus reached between them. If consensus could not be reached, another reviewer would have been invited to resolve consensus. We used the checklist developed by the *Canadian Medical Association Journal* to assess the quality of case reports¹⁰; Yang et al developed the checklist for case series¹¹; CONSORT (Consolidated Standards of Reporting Trials) was used for the clinical trials¹²; and QUORUM (Quality of Reporting of Meta-analyses) was used to evaluate the review articles.¹³ From the results of each checklist, if 25% or less of the criteria were addressed, the article was scored as *poor*; if 26% to 50% of the criteria were addressed, the article was scored as *fair*; if 51% to 75% of criteria were addressed, the article was scored as *good*; and if 76% to 100% of the criteria were addressed, the article was scored as *excellent*.

Results

We identified 1489 articles and found 62 to be potentially eligible (Fig 1). Of the 62 reports—17 were surveys/editorials/commentaries, 15 were case reports, 5 were case series, 8 were reviews, and 4 were clinical trials. There were a total of 13 reports that could not be included after reviewing the entire article: 7 had patients older than 6 years, 2 did not include OM, 2 did not have SMT as part of the interventions, and 2 had multiple reasons. Thus, 49 articles were included in the final evaluation. Tables 1 to 5 summarize the body of evidence for each reporting style.

There were 15 case reports (Table 1) included in this study. Each resulted in a decrease of OM symptoms or improved hearing. Thirteen of the articles involved chiropractic SMT, 1 used osteopathic care, and 1 described integrative care including chiropractic. The type of OM was described as definitely chronic in 9 of the articles and definitely acute in 3. Overall, the quality of the articles was fair; and there was no mention of adverse events.

Case series, described in Table 2, also demonstrated decreased recurrent symptoms or number of reoccurring episodes of OM. There were 4 articles that used chiropractic care and 1 that used osteopathic manipulative care. The exact definition of OM was different for each article. One article reported that there were no complications following care. In general, the quality of these articles was rated as good.

There were a total of 4 articles describing 3 different clinical trials (Table 3). One of the trials recruited acute OM patients (2 articles), 1 had chronic OM with effusion, and the final article recruited patients with recurrent OM. There were a total of 167 patients enrolled into these clinical trials, and most reported a decrease in symptoms. Two of the 3 clinical trials used osteopathic manipulation. Overall, the quality of the articles was excellent, with 2 of the articles reporting minor, transient adverse events.

The review articles' quality ranged from excellent (2) to good (2) to fair (3) (Table 4). All of the review articles were published in peer-reviewed journals during the past 10 years. The overarching summary statements of these articles varied greatly. One stated that SMT may decrease frequency of OM, another stated that the results are inconclusive, and another found no credible solid evidence.

The final table (Table 5) reports the list of commentaries (10), letters to editors (3), cross-sectional surveys (3), and protocols (1) on the subject of OM and

Table 1 Summary of included case reports

References	Peer reviewed?	Sample	Type of OM	Manipulative treatment	Results	Adverse events	Quality?
Stone-McCoy et al ¹⁴	Yes	Male; 9 mo	AOM	Chiropractic: toggle, activator, & cranial	No infection noted during the 6 wk of care and need for tubes was eliminated.	Not stated	Good
Cuthbert and Rosner ¹⁵	Yes	Female; 6 y	Recurrent AOM	Chiropractic: applied kinesiology	After 4 visits over 3 mo, ear infections resolved and had not returned over the following 2 y.	Not stated	Fair
Brown ¹⁶	Yes	Female; 3 y	OME	Chiropractic: diversified & activator	Marked resolution of bilateral ear pain and restoration of hearing confirmed with medical audiology reports.	Not stated	Good
Erickson et al ¹⁷	Yes	Male; 11 mo	Chronic OM	Integrative care: medical, homeopathic, & chiropractic	Reduced symptoms and fewer recurrences.	Not stated	Fair
Alcantara and Beattie ¹⁸	Yes	Male; 2 y	Chronic bilateral “glue ear”	Chiropractic adjustments	Abstract only. Improved tympanometric testing, speech, and auditory function.	Not stated	Poor
Saunders ¹⁹	Yes	Male; 3 1/2 y	Chronic OME	Chiropractic adjustment	Decreased discharge after initial treatment with improved hearing test after 3 mo.	Not stated	Good
Stenson ²⁰	No	Female; 5 y	Chronic OM	Chiropractic adjustments	Reduced occurrences.	Not stated	Poor
Hochman ²¹	No	2 Females; 2 & 4 y	Chronic OM	Chiropractic: sacral occipital technique & craniopathy	Improved symptoms after first treatment with no returned symptoms in 3 mo.	Not stated	Poor
Khorshid K ²²	No	Female; 3 y	Serous OM	Chiropractic: full spine diversified	After 1 mo of twice a wk care, her ears had “healed up.”	Not stated	Poor
Pratt-Harrington ⁷	Yes	Female; 14 mo	AOM	Osteopathic: Galbreath	Symptoms resolved. When recurrent symptoms began and were treated immediately, symptoms cleared up without any complications.	Not stated	Fair
Hough ²³	No	Female; 11 mo & Male; 7 mo	AOM	Chiropractic adjustments & endonasal procedures	Reduced symptoms and recurrence were resolved more quickly.	Not stated	Fair
Warner and Warner ²⁴	No	Female; 3 1/2 y	Chronic serous OM	Chiropractic: high-velocity, low-amplitude	Symptoms immediately began to improve and resolved after first mo of care.	Not stated	Poor
Amalu ²⁵	No	Male; 5 y	Chronic OM	Chiropractic: upper cervical	First month free of OM in 9 mo.	Not stated	Fair
Thomas ²⁶	Yes	Male; 11 mo	Not specified; possibly chronic OM	Chiropractic: diversified	Resolution of all symptoms.	Not stated	Poor
Phillips ²⁷	Yes	Female; 23 mo	Chronic OM	Chiropractic: activator	Symptoms cleared and remained clear for the following 4 y.	Not stated	Fair

AOM, Acute otitis media; mo, month(s); OM, otitis media; wk, week(s); y, year(s).

Table 2 Summary of included case series

References	Peer reviewed?	Sample	Type of OM	Manipulative treatment	Results	Adverse events	Quality?
Degenhardt and Kuchera ²⁸	Yes	5 Males, 3 Females; 7-35 mo	Recurrent OM	Osteopathic manipulative treatments	5 had no recurrence; 1 bulging tympanic membrane; 1 had 4 additional OM recurrences; 1 underwent surgery.	Not stated	Good
Zhang and Snyder ²⁹	Yes	12 Males, 9 Females; 9 mo-9 y	AOM	Chiropractic: toftness adjustments	Red, bulging tympanic membrane was found in all cases. 95% of the patients' tympanic membrane returned to normal after 1 adjustment.	Not stated	Fair
Fallon ³⁰	Yes	315 patients; 6 mo-5 y	127 AOM; 104 serous/chronic OM; 10 mixed OM	Chiropractic adjustments	% recurrence per diagnosis: 11% with acute; 16% with chronic; 30% with mixed; 18% with no diagnosis.	Not stated	Good
Fysh ³¹	Yes	3 Males, 2 Females; 13 mo-5 y	Chronic recurrent OM	Chiropractic adjustments	Each patient responded favorably to treatment by day 3 to week 8.	"No complications noted"	Excellent
Froehle ³²	Yes	46 patients; ≤ 5 y	Ear discomfort/ infection	Chiropractic: sacral occipital technique & modified applied kinesiology	93% of all episodes improved, with 75% improving within 10 d or less.	Not stated	Good

AOM, Acute otitis media; mo, month(s); OM, otitis media; y, year(s).

Table 3 Summary of included clinical trials

References	Peer reviewed?	OM defined	Sample	Manipulative treatment	Results	Adverse events	Quality?
Wahl et al ³³	Yes	Recurrent OM	84 pts: 21 double PBO, 20 OMT PBO & ech txt, 23 OMT txt & ech PBO, 20 OMT txt & ech txt	Osteopathic manipulation	No significance different in OM episodes between placebo and treatment groups.	Not stated	Excellent
Zaphiris et al ³⁴	Yes	AOM	57 pts: 25 txt, 32 control	Osteopathic manipulation	Abstract for Mills et al article. Txt group had decreased symptoms and improved tympanogram scores.	Not stated	Fair
Mills et al ³⁵	Yes	AOM	57 pts: 25 txt, 32 control	Osteopathic manipulation	Txt group had decreased symptoms and improved tympanogram scores.	"No adverse reactions to OMT were reported during the study."	Good
Sawyer et al ³⁶	Yes	Chronic OME	20 pts: 9 txt, 11 control	Chiropractic manipulation	Pilot study. Clinicians need more training with the tympanometry and otoscopic examination.	Soreness noted after 1 treatment, which resolved in a few days.	Excellent

AOM, Acute otitis media; ech, *echinacea purpurea*; OMT, osteopathic manipulative therapy; PBO, placebo; pts, participants; txt, treatment group.

Table 4 Summary of included review articles

Authors	Peer reviewed?	OM defined	Results	Comments	Quality?
Bronfort et al ³⁷	Yes	“...middle ear inflammation which can exist in an acute or chronic state and can occur with or without symptoms.”	“Inconclusive evidence in an unclear direction regarding the effectiveness of OMT for OM.”	Reviewed the following review articles: Hawk et al, Ernst et al, and Goltib et al; RCTs: Mills et al and Wahl et al	Excellent
Cole and Reed ³⁸	Yes	NA	“Limited data show that OMT may also be effective for non-spinal disorders.”	Reviewed Mills et al	Good
Ferrance and Miller ³⁹	Yes	AOM—“characterized by an abrupt onset of local signs such as ear pain or pressure, and systemic signs such as malaise or fever.”	“...there really is no credible solid evidence upon which to make recommendations regarding the use of chiropractic care in the treatment of acute OM.”	Stated that there was little evidence beyond case series, case reports, and 1 RCT (Mills et al) to support manipulative care for OM	Good
Alcantara et al ⁴⁰	Yes	NA	“...emphasized clinical management strategies in the care of children with OM.”	Abstract only. Reviewed 19 articles	Fair
Leighton ⁴¹	Yes	Recurrent chronic OM	“The evidence is inconclusive.... There is insufficient evidence to predict long-term outcomes.”	Reviewed the following case series: Fysh, Fallon, & Froehle; RCTs: Sawyer et al, Wahl et al, & Mills et al; mentioned numerous case reviews	Fair
Hawk et al ⁴²	Yes	Did not explicitly define	“Evidence was promising for the potential benefit....”	Reviewed the following RCTs: Mills et al & Sawyer et al; Case series: Fallon, Froehle, & Fysh; case reports: Peet, Phillips, & Thomas	Excellent
Carr and Nahata ⁴³	Yes	Upper respiratory tract infection	“...may decrease the frequency of episodes of acute OM in children....”	Reviewed Sawyer et al RCT	Fair
Ernst ⁴⁴	Yes	NA	“...the notion that chiropractic manipulation is an effective treatment of non-spinal pain syndromes is not based on conclusive evidence.”	Reviewed Sawyer et al RCT	Good

AOM, Acute otitis media; *NA*, not applicable; *OM*, otitis media; *OMT*, osteopathic manipulative therapy; *RCT*, randomized control trial.

Table 5 Summary of included commentaries, letters to editors, cross-sectional surveys, and protocols

References	Peer reviewed	Year	Type of article	Conclusion of SMT for OM	Comments
Steele et al ⁴⁵	Yes	2010	Protocol	An osteopathic manipulative medicine protocol can be administered to pediatrics with no serious adverse events.	Final outcomes from this trial should be out in late 2010.
Alcantara et al ⁴⁶	Yes	2010	Cross-sectional survey	15.6% responding DCs stated that ear, nose, and throat (ie, OM) conditions motivated a child's presentation to their office.	A total of 548/1550 members of the International Chiropractic Pediatric Association completed the survey.
Pohlman et al ⁴⁷	Yes	2010	Cross-sectional survey	Ear infections were reported with an average treatment frequency of 1 to 3 visits per month.	135/218 doctors of chiropractic with a diplomate in pediatrics completed this survey.
Hewitt et al ⁴⁸	Yes	2008	Commentary	A short course of chiropractic care may have a good effect to chronic OM.	This article included a description of CAM therapies that could be used in conjunction with SMT, a possible SMT mechanism of action, and a typical course of SMT care for OM.
Galgano ⁴⁹	Yes	2007	Letter to the editor	No conclusion.	Critique of "Reducing recurrent otitis media with OMT" by Degenhardt et al
Orenstein ⁵⁰	Yes	2007	Letter to the editor	OMT's impact on recurrent AOM needs an appropriately structured clinical trial; not enough information at this time to conclude.	Critique of "Reducing recurrent otitis media with OMT" by Degenhardt et al
Fallon ⁵¹	Yes	2004	Commentary	Removal of a subluxation, regardless of technique, could have impact on OM; a child with this condition should have his or her upper cervical area examined carefully.	The audio tract lectured about the guidelines for OM, recent research of SMT on OM, the pathophysiology of OM, examination procedures, physiology of the subluxation components, and appropriate adjustments.
Killinger ⁵²	Yes	2004	Commentary	Fallon demonstrated a compelling argument for SMT on OM, but further investigation on this topic is necessary.	Critique of "The role of chiropractic adjustment in the care and treatment of 332 children with OM" by Fallon.
Pichichero ⁵³	Yes	2003	Letter to the editor	Conclusions of the OMT for OM could not be drawn from the critiqued article.	Critique of "The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media" by Mills et al
No named author ⁵⁴	Yes	2002	Commentary	Did not state any conclusion.	Discussed the etiology for OM and standard treatment options. The article then discussed Fallon's case series and had some material and quotes from Fallon.
Warner ⁵⁵	Yes	2000	Commentary	SMT may reduce tight neck muscles, which could improve fluid drainage.	Gave quotes regarding research findings on antibiotics for OM and suggested that DCs communicate these with their patients.
Lamm and Ginter ⁵⁶	Yes	1998	Commentary	There are a number of interventions, including SMT, within the chiropractic scope of care, which can be done, with close monitoring, during an acute episode.	This article discussed epidemiology of OM, evaluation strategies, and possible management options. It also discussed a formal process that the Western States Chiropractic College clinical standards, protocols, and education committee used to gather and appraise available literature on this subject.
Bowers ⁵⁷	Yes	1997	Commentary	Stated that there are no current recommendations for SMT use on OM.	This article reviewed pediatric conditions and current practice guidelines.

DiGiorgi ⁵⁸	Yes	1997	Commentary	Cotreatment of pediatric OM between a pediatrician and a chiropractor is a valid option.	Described the different types of OM, anatomy of the ear, standards of care for OM, and how chiropractic care may affect OM.
Vallone and Fallon ⁵⁹	Yes	1997	Cross-sectional survey	24 different modalities were potentially used as a treatment by DCs for OM. Unanimous agreement for use of chiropractic adjustment of the atlas and the occiput, as well as removal of dairy/wheat from diet and manual lymphatic drainage.	Survey explored the management protocols of children with OM and asthma by 33 DCs enrolled into a postgraduate pediatric program.
Whiteside ⁶⁰	No	1993	Commentary	Experimentally, physiotherapist claims success with manipulation to cervical spine and massage of neck and shoulders.	Discussed cause for glue ear and potential management plans including CAM modalities.
Hendricks and Larkin-Thier ⁶¹	Yes	1989	Commentary	Proper alignment of the spine may return normal function of eustachian tube, but clinical trials are needed to verify this conclusion.	Reviewed anatomy of the ear, pathophysiology of OM, conventional care for OM.

AOM, Acute otitis media; *CAM*, complementary and alternative medicine; *DC*, doctor of chiropractic; *OM*, otitis media; *OMT*, osteopathic manipulative therapy; *RCT*, randomized clinical trial; *SMT*, spinal manipulation therapy.

SMT. Conclusions varied with the type of writing, but the majority supported the use of SMT for OM.

Discussion

Most of the literature from this narrative review comes from case reports, case series, surveys, and commentaries rather than RCTs of high quality. There appears to be a potential benefit from SMT in pediatric patients with OM; but more rigor needs to occur with quality of writing, reporting of adverse events, and reporting diagnosis and differential diagnosis.

For this review, the higher the literature was on the evidence pyramid, the better its quality. There are many books, commentaries, and checklists to help authors ensure that their manuscript adds value to the literature.⁶² However, writing is a difficult and time-consuming task. The quality of OM manuscripts could be improved tremendously if clarity regarding the mechanisms of SMT, how the diagnosis was reached, and reports of adverse events were included.

Few if any adverse events have been reported with SMT for the pediatric population.⁶³ Causation and incident rates have not been studied; so careful reporting of events, even minor, needs to be included when writing a manuscript. All checklists and other tools for writing manuscripts should include this item to ensure that authors are aware of its importance. When reported amongst the articles in this review, adverse effects were minor and transient.

Pichichero⁶⁴ has been writing about the importance of diagnostic accuracy of OM and its difficulties for several years. Ferrance and Miller³⁹ describe the 3 separate and distinct entities of OM and how they are typically differentiated by otoscopy with insufflation to check for appropriate movement of the tympanic membrane. This procedure requires rigorous training, and its difficulty is well known.

Clinical trials are most often designed to be explanatory or efficacy trials to determine whether an intervention has an effect under ideal circumstances.⁶⁵ Case reports classically occur in “real-world” clinical settings. The next step involves conducting effectiveness or pragmatic trials, which are intended to measure the degree of beneficial effect in a more “real-world” setting. A pragmatic clinical trial that explores the benefits of SMT in children with OM enhances its generalizability for clinical practitioners.⁶⁶ If these trials provide strong evidence for an intervention, establishing protocols for efficacy trials can be substantiated with the prior pragmatic trials’ intervention and clinical settings.

Limitations

This literature review has the inherent limitation of misleading conclusions. The use of more reviewers or a formalized analysis could have reduced potential bias and misleading conclusions. A second limitation of this review is the use of checklists. Checklists remove considerable subjectivity, but reviewer interpretation and limited criterion can lead to misjudgment or improper scoring of an article. Another limitation was that this was not a rigorous systematic review. We attempted to retrieve all relevant articles; but without using all the methods of a systematic review, we may have inadvertently missed some articles. The studies included in this literature review may not have included or accurately reported adverse events; thus, it is possible that adverse events were underreported.

Conclusions

From the 49 studies (17 surveys/editorials/commentaries, 15 case reports, 5 case series, 8 reviews, and 4 clinical trials) found in this report, there was limited quality evidence for the use of SMT for children with OM. There are currently no evidence to support or refute using SMT for OM and no evidence to suggest that SMT produces serious adverse effects for children with OM. More rigorous studies are needed to provide evidence and a clearer picture for both practitioner and patients.

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